510(k) SUMMARY

MAY 11 2005 K050252

MASIMO®
40 Parker
Irvine, CA 92618
Tel: 949-297-7000
Fax: 949-297-7001

Submitted by:	Masimo Corporation 40 Parker Irvine, CA 92618 (949) 297-7218 FAX (949) 297-7001
Company Contact:	James J. Cronin, Vice President, Regulatory Affairs/Quality Assurance
Date Summary Prepared:	April 16, 2005
Trade Name	AC-1 Adapter Cable, 8 Pin and 12 Pin Philips
Common Name	Cable, Transducer and Electrode
Classification Name and Product Code:	Cable, Transducer and Electrode (74DSA) (870.2900)
Substantially Equivalent Devices:	AC-1 Adapter Cable – K033349

Device Description

The AC-1 Adapter Cable, 8 pin and 12 pin Philips is fully compatible oximetry cable that allows the use of Masimo LNOP Sensors with Nellcor compatible pulse oximeter monitors from Philips. The cable represents a design change to the Masimo AC-1.

The AC-1 Adapter Cable, 8 pin and 12 pin Philips is similar in construction to the predicate device enabling the Masimo LNOP Sensors to be connected to Nellcor compatible pulse oximeter monitors from Philips.

Intended Use

The AC-1 Adapter Cables, 8 pin and 12 pin Philips used with Masimo LNOP Sensors are intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor) for adult, pediatric, infant, and neonatal patients in hospitals, hospital-type facilities, mobile, and home environments.

Technology Comparison

The AC-1 Adapter Cables, 8 pin and 12 pin Philips used with Masimo LNOP Sensors are substantially equivalent in intended use, design, principles of operation, materials, and performance to predicate sensors and operate on identical principles of non-invasive optical assessment of tissue oxygenation using emitters and detectors.

The AC-1 Adapter Cable is designed, configured, and manufactured for full compatibility with Nellcor and Nellcor compatible pulse oximeters using Masimo LNOP Sensors. The AC-1 Adapter Cable is constructed of similar materials and components of equivalent specifications as used in the predicate devices.

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The accuracy of the AC-1 Adapter Cables used with Masimo LNOP Sensors is equivalent to those of the predicate devices.

Performance Testing

Environmental Testing

Applicable environmental testing per the Reviewers Guidance for Premarket Submissions - November 1993, i.e. electrical, mechanical and environmental were performed and all tests passed

Clinical Testing

Clinical studies were performed using the AC-1 Adapter Cables, 8 pin and 12 pin Philips used with Masimo LNOP oximetry sensors on healthy adult volunteer subjects during no motion conditions who were subjected to a progressive induced hypoxia and measuring the arterial hemoglobin saturation value with the instruments against the arterial hemoglobin oxygen determined from arterial blood samples with a CO-Oximeter. Clinical testing of the LNOP sensors (except the LNOP TC-I) resulted in an accuracy of less than 2% SpO_2 A_{RMS} in the range of 70%-100% SaO_2 and 1% was added to account for the properties of fetal hemoglobin for the neonatal sensors. Clinical testing of the LNOP TC-I results in an accuracy of less than 3.5% SpO2 Arms in the range of 70% -100%.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2005

Mr. James J. Cronin
Vice President, Regulatory Affairs/Quality Assurance
Masimo Corporation
40 Parker
Irvine, California 92618

Re: K050252
Trade/Device Name: AC-1 Adapter Cable, 8 Pin and 12Pin Phillips
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: April 18, 2005
Received: April 21, 2005

Dear Mr. Cronin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: AC-1 Adapter Cable, 8 pin and 12 pin Philips

Indications For Use:

The AC-1 Adapter Cable, 8 pin and 12 pin Philips is indicated for the continuous noninvasive monitoring of functi oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor) for use with adult, pediatric, infant, and neonatal patients in hospitals, hospital-type facilities, mobile, and home environments.

Prescription Use ___X_____ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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